

Message

**From:** Gehlhaus, Martin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC091DA1FA684DD89435443C87C4F9A5-GEHLHAUS, MARTIN]  
**Sent:** 5/1/2014 7:39:12 PM  
**To:** Newhouse, Kathleen [Newhouse.Kathleen@epa.gov]; Strong, Jamie [Strong.Jamie@epa.gov]  
**Subject:** RE: Task for student services contractors  
**Attachments:** dermal carcinogenicity ET.docx

Completed table attached.

**From:** Newhouse, Kathleen  
**Sent:** Thursday, May 01, 2014 3:32 PM  
**To:** Gehlhaus, Martin; Strong, Jamie  
**Subject:** RE: Task for student services contractors

Thanks Marty, this is super helpful. I wasn't sure the other studies would have reported other dermal lesions. Here is the Schmahl study (attached). It is really annoying when HERO changes ID numbers...

**From:** Gehlhaus, Martin  
**Sent:** Thursday, May 01, 2014 2:50 PM  
**To:** Newhouse, Kathleen; Strong, Jamie  
**Subject:** RE: Task for student services contractors

I went through the dermal studies. See table below. Not very informative... only Sivak provided information about cytotoxicity. Also, the Schmahl HERO link doesn't work.

Reference and Study Design	Results <sup>a</sup>
<u>Poel (1959)</u> C57L mice: male (13–56/dose) 0, 0.15, 0.38, 0.75, 3.8, 19, 94, 188, 376, or 752 µg Dermal; 3 times/wk for up to 103 wks or until the appearance of a tumor by gross examination	Skin tumors (gross skin tumors and epidermoid carcinoma); dose-dependent decreased time of tumor appearance Incidences: Gross skin tumors: 0/33; 5/55; 11/55; 7/56; 41/49; 38/38; 35/35; 12/14; 14/14; and 13/13 Epidermoid carcinoma: 0/33; 0/55; 2/55; 4/56; 32/49; 37/38; 35/35; 10/14; 12/14; and 13/13 Cytotoxicity: information not provided
<u>Poel (1960)</u> SWR, C3HeB, or A/He mice: male (14–25/dose) 0, 0.15, 0.38, 0.75, 3.8, 19.0, 94.0, or 470 µg Dermal; 3 times/wk until mice died or a skin tumor was observed	Skin tumors and dose-dependent decreased time of first tumor appearance Incidences: SWR: 0/20; 0/25; 2/22; 15/18; 12/17; 16/16; 16/17; and 14/14 C3HeB: 0/17; 0/19; 3/17; 4/17; 11/18; 17/17; 18/18; and 17/17 A/He mice: 0/17; 0/18; 0/19; 0/17; 0/17; 21/23; 11/16; and 17/17 Cytotoxicity: information not provided
<u>Roe et al. (1970)</u> Swiss mice: female (50/dose) 0, vehicle, 0.1, 0.3, 1, 3, or 9 µg Dermal; 3 times/wk for up to 93 wks	Skin tumors; malignant skin tumors were observed in 4/41 and 31/40 mice in the two high dose groups, respectively incidences: 0/43; 0/47; 1/42; 0/42; 1/43; 8/41; and 34/46 Cytotoxicity: information not provided
<u>Schmidt et al. (1973)</u> NMRI mice: female (100/group) Swiss mice: female (100/group)	Skin tumors (carcinomas) incidences: NMRI:

Reference and Study Design	Results <sup>a</sup>
0, 0.05, 0.2, 0.8, or 2 µg Dermal; 2 times/wk until spontaneous death occurred or until an advanced carcinoma was observed	2/100 at 2 µg (papillomas); 2/100 at 0.8 µg and 30/100 at 2 µg (carcinomas) Swiss: 3/80 at 2 µg (papillomas); 5/80 at 0.8 µg and 45/80 at 2 µg (carcinomas) Cytotoxicity: information not provided
<u>Schmähl et al. (1977a)</u> NMRI mice: female (100/group) 0, 1, 1.7, or 3 µg Dermal; 2 times/wk until natural death or until they developed a carcinoma at the site of application	Skin tumors (papillomas and carcinomas) incidences: 0/81; 1/77; 0/88; and 2/81 (papillomas) 0/81; 10/77; 25/88; and 43/81 (carcinomas) Cytotoxicity:
<u>Habs et al. (1980)</u> NMRI mice: female (40/group) 0, 1.7, 2.8, or 4.6 µg Dermal; 2 times/wk until natural death or gross observation of infiltrative tumor growth	Skin tumors and dose-dependent increase in age-standardized tumor incidence incidences: 0/35; 8/34; 24/35; and 22/36 age-standardized tumor incidence: 0, 24.8, 89.3, and 91.7% Cytotoxicity: information not provided
<u>(Grimmer et al. (1984); Grimmer et al. (1983))</u> CFLP mice: female (65–80/group) 0, 3.9, 7.7, or 15.4 µg (1983 study) 0, 3.4, 6.7, or 13.5 µg (1984 study) Dermal; 2 times/wk for 104 wks	Skin tumors (papillomas and carcinomas) with a decrease in tumor latency incidences: 1983: 0/80; 7/65; 5/64; and 2/64 (papillomas) 0/80; 15/65; 34/64; and 54/64 (carcinomas) 1984: 0/65; 6/64; 8/65; and 4/65 (papillomas) 0/65; 37/64; 45/65; and 53/65 (carcinomas) Cytotoxicity: information not provided (1983 and 1984)
<u>Habs et al. (1984)</u> NMRI mice: female (20/group) 0, 2, or 4 µg Dermal; 2 times/wk for life	Skin tumors (papillomas and carcinomas) with a decrease in mean survival time incidences: 0/20; 2/20; and 0/20 (papillomas) 0/20; 7/20; and 17/20 (carcinomas) Cytotoxicity: information not provided
NIOSH (1989) ( <u>Sivak et al. (1997); Arthur D Little, 1989</u> ) C3H/HeJ mice: male (30/group) 0, 0.05, 0.5, or 5 µg Dermal; 2 times/wk for up to 104 wks	Skin tumors (papillomas and carcinomas) incidences: 0/30; 0/30; 5/30 (1 papilloma, 1 keratoacanthoma, 3 carcinomas); and 27/30 (1 papilloma, 28 carcinomas) Cytotoxicity: 5 µg dose group had an incidence of 80% of scabs and sores

**From:** Newhouse, Kathleen

**Sent:** Thursday, May 01, 2014 12:13 PM

**To:** Gehlhaus, Martin; Strong, Jamie

**Subject:** RE: Task for student services contractors

Yes, I'm looking for information from the publications regarding dermal lesions/direct cytotoxicity to add to the dermal cancer evidence table. I'm interested in the doses related to the lesions and what type(s) of lesion observed (if reported).

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**From:** Gehlhaus, Martin  
**Sent:** Thursday, May 01, 2014 12:07 PM  
**To:** Newhouse, Kathleen; Strong, Jamie  
**Subject:** RE: Task for student services contractors

So what you're looking for is information in the dermal evidence tables that documents whether cytotoxicity was observed or not, and if so, at what doses: correct?

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**From:** Newhouse, Kathleen  
**Sent:** Thursday, May 01, 2014 11:36 AM  
**To:** Gehlhaus, Martin; Strong, Jamie  
**Subject:** RE: Task for student services contractors

If you had time Marty, that would be excellent. Plus, you are familiar with the BaP comments regarding this issue.

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**From:** Gehlhaus, Martin  
**Sent:** Thursday, May 01, 2014 7:45 AM  
**To:** Newhouse, Kathleen; Strong, Jamie  
**Subject:** RE: Task for student services contractors

If we are pressed for time I can take a shot at this.

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**From:** Newhouse, Kathleen  
**Sent:** Wednesday, April 30, 2014 3:41 PM  
**To:** Strong, Jamie  
**Cc:** Gehlhaus, Martin  
**Subject:** Task for student services contractors

Hi Jamie. I think you asked previously if we had any tasks for the student services contractors...I have thought of one.

## Ex. 5 Deliberative Process (DP)

Let me know how I need to work through to get them started (Teneille?). If they have access to HERO, they should be able to follow the links below to download the papers.

-Kathleen

Studies:

([Grimmer et al., 1984](#); [Habs et al., 1984](#); [Grimmer et al., 1983](#); [Habs et al., 1980](#); [Schmähl et al., 1977a](#); [Schmidt et al., 1973](#); [Roe et al., 1970](#); [Poel, 1960, 1959](#)).